## REMARKS

Applicants respectfully request reconsideration of the application in view of the following remarks.

Claims 1-13 are pending in the application, with claims 1, 7, and 12 being independent claims. Claims 1-13 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 96/19186 ("the Sun PCT") in view of U.S. Patent No. 5,661,170 ("the Chodosh patent").

### *Interviews*

Applicants would like to thank the Examiner for working with Applicants to clarify the record with respect to the non-finality of the instant Office Action. As noted in the Interview Summaries dated January 18, May 4, and June 1, 2006, the Non-Final Office Action dated May 10, 2006 has replaced the Non-Final Office Action dated January 18, 2006, and the Office Actions dated July 28, 2005 and January 18, 2006 have been withdrawn.

### *New Matter Objection*

The Examiner objects to the Amendment filed October 28, 2005[1] under 35 U.S.C. §132(a), which prohibits introducing new matter into the disclosure of the invention. The Amendment in question amended claims 1 and 7 to recite, in part, "administering to a nail area of a patient a composition that is effective for treating onychomycosis and that *comprises urea as the sole active antifungal ingredient*." Independent method claim 12 was amended to read "administering to a nail area of a patient a composition *comprising urea as the sole active antifungal ingredient*. . . wherein the urea is present in an amount therapeutically effective for treating onychomycosis." With respect to this Amendment, the Examiner asserts that "[a]pplicant fails to provide support for 'urea as the sole active antifungal ingredient' in the

[1] Applicants respectfully note that the Amendment in question was actually filed on May 13, 2005. The Response to Office Action filed October 28, 2005 did not amend the claims.

Specification." Office Action, page 2 (emphasis in original). The Examiner requires that the new matter be cancelled.

Applicants respectfully traverse this rejection. Applicants' specification and claims, as originally filed, disclose compositions containing urea as the sole active antifungal ingredient and therefore fully support the claim recitation, "urea as the sole active antifungal ingredient."

Applicants' specification discloses compositions comprising urea as the "sole active ingredient." Applicants' specification states, "[w]e have recently found urea to be useful as the sole active ingredient in topically treating onychomycosis." Applicants' specification, page 2, lines 1-2. The specification further states that "[t]his has been described in our co-pending application Serial No. 10/103,213 of March 20, 2002," which is incorporated in the present specification by reference." *Id.*, lines 2-3. The '213 application states, "[t]hus, the present invention provides a method of treating onychomycosis in a topical composition containing urea as its sole active ingredient." Application Serial No. 10/103,213, para. [0018]. Applicants' specification also discloses that in these compositions, urea is used as an antifungal agent: "[w]e have found urea to be an antifungal agent of equal potency to known antifungal agents. . . . Thus, the present invention provides . . . a topical composition containing urea as the antifungal agent." Applicants' specification, page 4, lines 14-18.

Accordingly, Applicants' specification discloses compositions in which urea is used as an antifungal agent and is the sole active ingredient. Such compositions do not include any other active ingredient, let alone another active antifungal ingredient besides urea. All other ingredients in such compositions must be inactive, and therefore cannot be active antifungal agents. Applicants' specification therefore discloses compositions comprising "urea as the sole active antifungal ingredient."

Applicants' specification makes it clear in other ways that compositions of the present invention comprise urea -- as opposed to other possible antifungal agents -- as the sole antifungal agent. Applicants' specification states:

> Antifungal agents known to be useful for the treatment of onychomycosis include but are not limited to: topical creams, ointments, solutions, lacquers and gels containing as active agents, for example, . . . , bifonazole, . . . , isoconazole, ketoconazole, [and] miconazole nitrate.... The above antifungal topical compositions are known to those skilled in the art.
>
> We have found urea to be an antifungal agent of equal potency to known antifungal agents. Urea was long known for tissue softening and treating dry skin, without the need of traditional preservatives.
>
> Thus, the present invention provides a method of treating onychomycosis in a topical composition *containing urea as the antifungal agent.*

Applicants' specification, page 4, lines 7 - 18 (emphasis added).

In the last sentence of the above passage, the use of the word "the" before "antifungal agent" would lead a person of ordinary skill in the art to understand that the topical compositions in question contain urea as the sole antifungal agent.[2] If other antifungal agents were contemplated for use in the claimed composition, the phrase would read "urea as an antifungal agent," instead.

In addition, the "most preferred embodiment" of Applicants' specification is a composition comprising urea as the sole active antifungal ingredient, with the following ingredients and relative weights:

| Ingredient | % W/W |
|---|---|
| Tocophenyl Acetate (Vitamin E) | 3.0 |
| Urea USP | 40.4 |
| Carbopol 940 | 0.20 |
| Petrolatum | 8.94 |
| Mineral oil | 7.1 |
| Glyceryl stearate | 2.88 |

[2] Similarly, the methods of treating onychomycosis recited in original claims 1, 7, and 12 also involve "composition[s] comprising urea as *the* active antifungal ingredient" (emphasis added). In the same way, one of ordinary skill in the art would understand these claims to involve compositions comprising urea as the *sole* active antifungal ingredient.

| | |
|---|---|
| Cetyl alcohol | 1.63 |
| Propylene glycol | 2.00 |
| Xanthum gum | 0.05 |
| Trolamine | 0.10 |
| Purified Water Q.S. | 100.00. |

Applicants' specification, page 8, lines 15-18. Notably, this composition does not comprise any antifungal agent other than urea. Accordingly, Applicants' preferred embodiment supports the recitation in the claims of a "composition comprising urea as the sole active antifungal agent."

For at least these reasons, Applicants submit that Applicants' specification and claims as originally filed fully support the recitation of a "composition comprising urea as the sole active antifungal agent," and satisfy the written description requirement of 35 U.S.C. §112 with respect to all claim features of the pending claims. Accordingly, Applicants respectfully request that the Examiner withdraw the instant rejection.

***§ 103 Rejection***

The Examiner has rejected claims 1-13 under 35 U.S.C. § 103(a) as being unpatentable over WO 96/19186 ("the Sun PCT") in view of U.S. Patent No. 5,661,170 ("the Chodosh patent"). Applicants respectfully traverse this rejection.

In contrast to the claimed invention, the Sun PCT teaches using urea as a permeation enhancer to enhance permeation of an antifungal agent, such as itraconazole, ketoconazole, or miconazole nitrate. Urea is not even listed among "antifungal drugs that can be used in the invention" described in the Sun PCT (page 7, line 35 to page 8, line 5). The Sun PCT states that "urea's principal contribution to the efficiency of the formulation used in the invention is to inhibit the nail keratin from returning to its original densely packed cross-linked state . . . so that the nail remains more permeable to the antifungal drug over a longer period of time" (page 8, lines 17-23).

Each of "representative formulations" A through F and H through L in the Sun PCT includes, in addition to urea, one of the "preferred" antifungal drugs miconazole nitrate and itraconazole. Another "representative formulation," formulation G, contains the antifungal drug miconazole nitrate but not urea. Formulation G is meant to be used after the nail has been pre-treated with urea, and there is no teaching or suggestion that such pre-treatment is, in itself, effective for treating onychomycosis. Nowhere does the Sun PCT recognize that urea can be an effective antifungal ingredient, much less that it can be the sole active antifungal ingredient in a composition effective for treating onychomycosis. The Sun PCT explicitly discloses many antifungal drugs that are all different from urea, and that urea is present to enhance permeation of these different antifungal drugs through nail tissue.

Thus, in contrast to the claimed invention, the Sun PCT does not teach or suggest that the urea is present in a composition in an amount therapeutically effective for treating onychomycosis, or that urea is the sole active antifungal ingredient in a composition effective for treating onychomycosis.

Applicants submit that the independent claims patentably distinguish the claimed invention over the Sun PCT due to their recitation of administering "a composition that is effective for treating onychomycosis and that comprises urea as the sole active antifungal ingredient" (claims 1 and 7) or administering "a composition comprising urea as the sole active antifungal ingredient. . . wherein the urea is present in an amount therapeutically effective for treating onychomycosis" (claim 12).

Additionally, Applicants submit that the Chodosh patent also does not teach or suggest using urea as the sole active antifungal ingredient in a composition effective for treating onychomycosis. The Chodosh patent discloses that "imidazolidinyl urea" and "diazolidinyl urea" are "common preservatives" (col. 6, lines 6-8 and col. 7, lines 8-9). As shown in Tables 2 and 3 of the Chodosh patent, diazolidinyl urea may be present in the disclosed compositions in amounts of up to 1.0 wt%. Nowhere does the Chodosh patent mention "urea" as opposed to the preservatives "imidazolidinyl urea" and "diazolidinyl urea." Nor does the Chodosh patent teach or suggest urea as an effective antifungal ingredient or as the sole antifungal agent in a

composition for treating onychomycosis. Thus, the independent claims patentably distinguish the present invention over the Sun and Chodosh documents, whether those documents are taken individually or in combination.

In the Office Action, the Examiner also states that "[s]ince the prior art [Sun PCT reference] clearly teaches the use of the same component [urea], the beneficial results and properties imparted by that particular component [urea] would also be the same." Office Action, page 6. Applicants respectfully submit that it is improper to look to the present application to find a reasonable expectation of success and to use such finding as a basis for rejecting the present claims under 35 U.S.C. § 103(a). Neither the Sun PCT nor the Chodosh patent would have motivated one of ordinary skill in the art to think that urea could be used as the sole active antifungal ingredient in a composition therapeutically effective for the treatment of onychomycosis. It is the present application, not the references of record, which teaches that urea can be so used and result in effective treatment of onychomycosis.

In the Office Action, the Examiner also attempts to address Applicants' argument that the prior art of record does not teach "urea as the sole active antifungal ingredient." The Examiner states:

> Regarding Applicant's argument that "Sun et al. do not teach urea as the sole active antifungal ingredient in a composition effective for treating onychomycosis", the Examiner points out that there is lack of support for the limitation of urea as the sole active antifungal ingredient.... Furthermore, Applicants have not demonstrated that the inclusion of additional active components in the prior art references, would be detrimental or adversary if utilized in the invention claimed herein.

Office Action, page 6 (emphasis in original). As discussed above, however, there is adequate support in the specification for the limitation of urea as the sole active antifungal agent in the present claims. Moreover, the question of whether the "sole active antifungal" recitation lacks support is not relevant to whether the asserted combination of references renders the claimed invention unpatentable over the Sun PCT and the Chodosh patent under 35 U.S.C. § 103. In any event, as discussed above, the cited references do not provide a basis for a finding that the present claims are obvious under 35 U.S.C. § 103. Thus, it is not necessary for Applicants to

demonstrate whether including additional active components in the claimed invention would be detrimental.

The Examiner goes on to conclude that "[i]t is the position of the Examiner that the prior art explicitly teaches a similar method for treating nail fungal conditions, such as onychomycosis, by incorporating similar components that are used for the same field of endeavor as that desired by Applicant." *Id.* However, the use of "similar components" used for the "same field of endeavor" does not establish or even provide substantial evidence of obviousness under 35 U.S.C. § 103(a). The Examiner has not established that the cited references disclose or suggest "urea as the sole active antifungal ingredient," as recited or incorporated in all the claims.

Finally, the Examiner has taken the position that "Applicants have not demonstrated any unusual and/or unexpected results through the instantly claimed combination of ingredients." Office Action, page 7. Applicants respectfully submit that because the Examiner has not established a prima facie case of obviousness under 35 U.S.C. § 103(a), Applicants need not submit evidence of unexpected results to rebut it. At any rate, in the '213 application, incorporated by reference in the present specification, it is stated that "[w]e have now surprisingly found urea to be an antifungal agent of equal potency to known antifungal agents." Application Serial No. 10/103,213, para. [0017]. This finding amply addresses the Examiner's concern.

For at least the above reasons, Applicants submit that the Section 103(a) rejection of the independent claims cannot properly be maintained. Applicants further submit that the dependent claims are patentable, for the same reasons that the base claims from which they depend are patentable, and further due to the additional features that they recite. Individual consideration of each dependent claim is respectfully requested.

Applicants believe that a full and complete response has been made to the outstanding Office Action and that, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

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Respectfully submitted,

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